BSI-320US1 PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Juan Carlos Parodi : Art Unit:

Application No.: To Be Assigned : Examiner:

Filed: Herewith :

FOR: STENT GRAFT DEVICE FOR TREATING : ABDOMINAL AORTIC ANEURYSMS :

#### Which is a continuation of:

Applicant: Juan Carlos Parodi : Art Unit: 3738

Application No.: 09/139,957 : Examiner: M. Milano

Filed: August 25, 1998 :

FOR: STENT GRAFT DEVICE FOR TREATING :

ABDOMINAL AORTIC ANEURYSMS

# PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, DC 20231

SIR:

Prior to examination, please amend the above-identified application as follows.

## IN THE SPECIFICATION:

At page 1, after "BACKGROUND OF THE INVENTION", insert -- This application is a continuation of U.S. Patent Application No. 09/139,957, filed August 25, 1998 (status: pending).--

At page 1, line 6, please replace "Aorta" with --aorta--.

At page 1, line 7, please replace "Aorta" with --aorta--.

At page 3, line 16, please replace "my" with --may--.

At page 3, line 21, please replace "aorta" with --aortic--.

At page 3, line 26, please replace "aorta" with --aortic--.

BSI-320US1 - 2 -

At page 4, line 8, please delete "the" prior to "practice".

At page 4, line 24, please replace "responsible of" with -- responsible for--.

At page 5, line 4, please replace "accommodated to" with --accommodated in--.

At page 5, lines 8 - 19, please replace the entire paragraph beginning "It is therefore . . ." and ending ". . . retained within the iliac arteries." with the following paragraph:

--It is therefore one object of the present invention to provide a stent graft device for location within an aorta having an inner diameter and its bifurcation into iliac arteries each having an inner diameter, the aorta inner diameter being smaller than a sum of the iliac inner diameters. The graft comprises a proximal main tubular portion to be retained within an upper portion of the aorta, the proximal main tubular portion having a first diameter and being divided into two tubular limbs, each limb having a second diameter and a distal end portion to be located inside an associated iliac artery and to be held against an inner surface of the iliac artery. The distal end portion defines a third diameter larger than the second diameter, the second diameter being of an effective size such that the two tubular limbs can be accommodated within the aorta inner diameter without restriction. The stent graft device may be unitary, which means that the device comprises a single-piece, non-modular construction.--

At page 5, line 22, please replace "Aorta" with --aorta--.

At page 5, line 22, please replace "Iliac" with --iliac--.

At page 6, line 16, please replace "Aorta" with --aorta--.

At page 7, line 16, please replace "know" with --known--.

At page 12, lines 2-12, please replace the entire paragraph beginning "A stent graft device . . ." and ending ". . . retained within the iliac arteries." with the following paragraph:

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--A stent graft device has an upper main tubular portion dividing into two tubular limbs and is adapted for location in an aorta having an aneurysm. The stent graft device is well suited for an aorta having a restricted section having an inner diameter smaller than the sum of the inner diameters of the iliac arteries, which branch from the aorta. The diameters of the two tubular limbs are sufficiently small to allow for both tubular limbs to be deployed side-by-side in a fully expanded state within the restricted section without being constrained by the aorta inner surface. The limbs also have distal end portions having diameters larger than the diameters of limbs at the area near the restricted section for being retained within the iliac arteries.--

## IN THE CLAIMS:

Please cancel claims 1-6 and add the following new claims.

- 7. An endoluminal device for deployment within a first lumen comprising a restricted section having an inner surface with an inner diameter and a bifurcation into branch lumen each having an inner surface with an inner diameter, the restricted section inner diameter being smaller than a sum of the branch lumen inner diameters, the device comprising a proximal main tubular portion to be retained within a proximal portion of the first lumen and having a first diameter and two tubular limbs depending from the proximal main tubular portion, each limb having a second diameter and a distal end portion for deployment inside one of the branch lumen against the branch lumen inner surface, the distal end portion defining a third diameter larger than the second diameter, wherein the sum of the two second diameters is less than the restricted section inner diameter and each tubular limb comprises a concave transition portion extending from the second diameter to the third diameter.
- 1 8. The stent graft device of claim 7, wherein the distal end 2 portion is cylindrical.
- 9. The device of claim 7, wherein the second diameter is smaller than the branch lumen inner surface diameter and the third diameter, in an unconfined state, is larger than the branch lumen inner surface diameter.
  - 10. The device of claim 7, wherein the device is unitary.

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1	11. The device of claim 7 wherein the device has a fully expanded
2	configuration and a compressed configuration and the distal end portion third
3	diameter is constrained from reaching the fully expanded configuration by the branch
4	lumen inner surface and the second diameters of the two tubular limbs are
5	sufficiently small to allow both tubular limbs to be deployed side-by-side in their
6	fully expanded configuration within the first lumen restricted section without being
7	constrained by the restricted section inner surface.

12. A method of treating an afflicted portion of a branched lumen, the method comprising the steps of:

identifying a first lumen comprising a restricted section having an inner surface with an inner surface diameter and a bifurcation into branch lumen each having an inner surface with an inner surface diameter, the first lumen inner surface diameter being smaller than the sum of the branch lumen inner surface diameters,

implanting an endoluminal device comprising a proximal main tubular portion having a first diameter and two tubular limbs depending from the main tubular portion, each limb having a second diameter and a distal end portion, the distal end portion having a third diameter larger than the second diameter and, at a location such that: (i) said main proximal portion is disposed within a proximal portion of the first lumen; (ii) each of said tubular limbs is disposed inside an associated branch lumen; and (iii) the distal end portion is disposed within one of said branch lumen and restricted from full expansion by the branch lumen inner surface, wherein the second diameters of each of said two tubular limbs are sufficiently small to allow both tubular limbs to be deployed side-by-side in a fully expanded state within the restricted section inner diameter without being constrained by the first lumen inner surface and wherein each tubular limb comprises a concave transition portion extending from the second diameter to the third diameter.

- 13. An endoluminal device for deployment within a first lumen having a restricted section and a bifurcation into branch lumen, the device comprising:
- a proximal main tubular portion to be retained within a proximal portion of the first lumen; and

a first and a second tubular limb depending from said proximal main

- 7 tubular portion;
- 8 wherein each of said first and second tubular limbs comprises: (i) an elongated
- 9 portion for extending across the restricted section and having a first diameter; (ii) a
- distal end portion to be located inside an associated branch lumen and to be held
- against an inner surface of the branch lumen, the distal end portion defining a
- second diameter larger than the first diameter; and (iii) a concave transition portion
- extending between the elongated portion and the distal end portion.

Respectfully submitted,

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Dated: January 18, 2001

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The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

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Kathleen Libby